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EXAMINER	
FISHER, ABIGAIL L	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/017,259	DELRIEU ET AL.	
	Examiner	Art Unit	
	ABIGAIL FISHER	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-45,47-62,64 and 65* is/are pending in the application.

4a) Of the above claim(s) *47-62 and 65* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-45 and 64* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The examiner for your application in the USPTO has changed. Examiner Abigail Fisher can be reached at 571-270-3502.

Claims 1-18, 46 and 63 were/stand cancelled. Claim 19 was amended. Claims 19-45, 47-62 and 64-65 are pending. Claims 47-62 and 65 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on August 18 2003. Claims 19-45 and 64 are directed to the elected invention.

Prosecution on the merits of this application is reopened on claims 19-45 and 64 considered unpatentable in view of the newly discovered reference(s) to Bretz et al. (WO 98/04618). Rejections based on the newly cited reference(s) follow.

Terminal Disclaimer

The terminal disclaimer filed on 12/20/05 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US Patent No. 5961990 has been reviewed and is accepted. The terminal disclaimer has been recorded.

The terminal disclaimer filed on 2/13/04 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US Patent No. 6319507 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 32-35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification discloses chemicals, such agar and polysaccharides, which meet the written description and enablement provisions of 35 USC 112, first paragraph. However, claim(s) 32 is(are) directed to encompass **synthetically modified polysaccharides, synthetically modified proteins, synthetic polymers, natural polymers, and botanically derived gels**, which only correspond in some undefined way to specifically instantly disclosed chemicals. None of these synthetically modified polymers, synthetic polymers, natural polymers, and botanically derived gels, meet the written description provision of 35 USC § 112, first paragraph, due to lacking chemical structural information for what they are and chemical structures are highly variant and encompass a myriad of possibilities. The specification provides insufficient written

description to support the genus encompassed by the claim. **Note: MPEP 2163.**

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, (Fed. Cir. 1991), makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

Univ. of Rochester v. G.D. Searle, 69 USPQ2d 1886, 1892 (CAFC 2004), further supports this by stating that:

> The appearance of mere indistinct words in a specification or a claim, even an original claim, does not necessarily satisfy that requirement. A description of an anti-inflammatory steroid, i.e., a steroid (a generic structural term) described even in terms of its functioning of lessening inflammation of tissues fails to distinguish any steroid from others having the same activity or function. A description of what a material does, rather than of what it is, usually does not suffice.... The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. (Emphasis added).

With the exception of the above specifically disclosed chemical structures, the skilled artisan cannot envision the detailed chemical structure of the encompassed synthetically modified polymers, synthetic polymers, natural polymers, and botanically derived gels, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The chemical structure itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (Fed. Circ. 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016, (Fed. Cir. 1991). In Fiddes v. Baird, 30 USPQ2d 1481, 1483, (Bd. Pat. App. & Int. 1993), claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence. Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 (Fed. Cir. 1997) held that:

> ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using

> "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

Furthermore, to the extent that a functional description can meet the requirement for an adequate written description, it can do so only in accordance with PTO guidelines stating that the requirement can be met by disclosing "sufficiently detailed, relevant identifying characteristics," including "functional characteristics when coupled with a known or disclosed correlation between function and structure." Univ. of Rochester v. G.D. Searle, 68 USPQ2d 1424, 1432 (DC WNY 2003).

Therefore, only the above chemically structurally defined chemicals, but not the full breadth of the claim(s) meet the written description provision of 35 USC § 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC § 112 is severable from its enablement provision. (See page 1115.)

Claims 19-45 and 64 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.

The specification, while being enabling for agar, does not reasonably provide enablement for all synthetic polymers, vinyl polymers and copolymers, natural polymers, proteins and gels. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

To be enabling, the specification of the patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. In re Wright, 999 F.2d 1557, 1561 (Fed. Cir. 1993). Explaining what is meant by "undue experimentation," the Federal Circuit has stated:

> The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the claimed invention. PPG v. Guardian, 75 F.3d 1558, 1564 (Fed. Cir. 1996).[1]

The factors that may be considered in determining whether a disclosure would require undue experimentation are set forth by In re Wands, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing Ex parte Formal, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,
2) the amount of direction or guidance provided,
3) the presence or absence of working examples,
4) the nature of the invention,
5) the state of the prior art,
6) the relative skill of those in the art,
7) the predictability of the art, and
8) the breadth of the claims.

These factors are always applied against the background understanding that scope of enablement varies inversely with the degree of unpredictability involved. In re Fisher, 57 CCPA 1099, 1108, 427 F.2d 833, 839, 166 USPQ 18, 24 (1970). Keeping that in mind, the Wands factors are relevant to the instant fact situation for the following

reasons:

The nature of the invention, relative skill level, and breadth of the claims

The instant invention is directed to a method of preparing gel particles comprising forming a hot aqueous solution of a polymeric gelling agent.

The complex nature of the claims is greatly exacerbated by the breath of the claims. The claims encompass a large genus of polymers including synthetic polymers, vinyl polymers, natural polymers, polysaccharides, proteins etc.

The relative skill of those in the art is high, that of an MD or PHD.

The state and predictability of the art

As illustrative of the state of the art, the examiner cites Sperling (Introduction to Physical Polymer Science, 2001) and Morganti (US Patent No. 4834734).

The state of the art recognizes that not all polymers are water soluble. For example methanol and water are known not to dissolve polybutadiene or polystyrene. Furthermore it is known that the solubility of a polymer also depends on its molecular weight. Therefore, it is reasonable that a polymer may be soluble in water at one particular molecular weight and not soluble in another (Sperling, page 66, section 3.2.1). Collagen for example is known in forms to be both water soluble and water insoluble (Morganti, column 2, lines 15-21).

The lack of significant guidance from the specification or the prior art with regard to use as to which polymers of the genus claimed would be water soluble makes

[1] As pointed out by the court in In re Angstadt, 537 F.2d 498 at 504 (CCPA 1976), the key word is "undue", not "experimentation".

practicing the invention unpredictable. The instant specification teaches that agar (agarose) is a water soluble polymer that can be utilized in the invention. However, the instant specification provides no guidance as what other polymers are water soluble other than stating the broad genus of polymers taught in instant claim 32.

The amount of direction or guidance provided and the presence or absence of working examples

The specification provides no direction or guidance for what synthetic or natural polymers are water soluble. Due to the vastness of compounds classified as gelling agents, one of ordinary skill would undergo undue experimentation in deducing which polymers are actually soluble within applicant's scope.

The working examples of the specification are directed towards utilizing agar. However, the examples do not enable one to utilize any polymer in the method as instantly claimed.

The quantity of experimentation necessary

Because of the known unpredictability of the art, and in the absence of experimental evidence, no one skilled in the art would accept the assertion that the instantly claimed polymers could be predictably used as gelling agents as inferred by the claim and contemplated by the specification. Accordingly, the instant claims do not comply with the enablement requirement of §112, since to practice the invention claimed in the patent a person of ordinary skill in the art would have to engage in undue experimentation, with no assurance of success.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19-45 and 64 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "hot" in claim 19-21, 25, 27, 30 and 37 is a relative term which renders the claim indefinite. The term "hot" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Hot can be interpreted differently by different people, as some of ordinary skill in the art would interpret 50 °C as hot whereas other may interpret hot to a boiling solution closer to 100 °C. The instant specification provides to guidance as to what temperature or temperature ranges constitute "hot".

The term "cold" in claim 19-22, 25, 27, 30, 38 and 41- 44 is a relative term which renders the claim indefinite. The term "cold" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Cold can be interpreted differently by different people. Cold could be interpreted as a temperature lower than the "hot solution" or cold can be interpreted as 0°C or less. The instant specification provides to guidance as to what temperature or temperature ranges constitute "cold".

Claim 24 recites that the conduit has a cross-section area of from about 4 to about 100 times the cross-sectional area of the injection tube. The claim then goes on to recite optionally 25 times. The claim is indefinite because optionally indicates that there does not need to be a cross-sectional area ratio while line 2 of the claim indicates that there has to be a particular ratio of the cross-section. Furthermore if optionally is interpreted to be present then 25 times is a narrower limitation than the cross-sectional ratio indicated earlier in the claim. This interpretation of the claim renders the claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims.

Claim 32 as currently written is vague and indefinite. The claim recites that the gelling agent comprises a pH stable water-soluble polymer "optionally selected from the group consisting of" creates uncertainty as to what is being claimed. It appears applicants are attempting to claim specific polymers as a Markush group. A Markush group by definition is closed and are permitted if they present no uncertainty or ambiguity with respect to the question of scope or clarity of the claim. **Note: MPEP 2173.05(h).** The presence of the word "optionally" however, creates uncertainty or ambiguity with respect to the scope because it indicates that the polymer listed in the claim are suitable but that others would also acceptable.

Claim 32 as currently written is vague and indefinite. It is unclear what "botanically derived gel" are referring to. Applicants have provided no definition of

botanically derived gels nor given any examples as what constitutes a botanically derived gel.

Claims 33 and 35 as currently written are vague and indefinite. The claims recite "restraining polymer". The instant specification provides no definition for what constitutes a restraining polymer. The instant specification indicates specific polymers that are considered to fall under the genus of "restraining polymer". However, without a clear definition it is unclear what are the metes and bounds of the patent protection desired for restraining polymer. The specification indicates that the polymer may bind the active but this does not appear to be a requirement (pages 16-20 of the specification). Therefore, without guidance as to the meaning of restraining polymer the resulting claim is indefinite.

Claim 35 as currently written is vague and indefinite. The claims recites "labile active agent". It is unclear what is meant by labile active agent. Is it labile due to pH sensitivity or because of cleavable bond?

Claim 42 recites the limitation "the discharge size" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 42 recites the limitation "the velocity" in line. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 19-32, 37-45 and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bretz et al. (WO 98/04618) in view of Brandau et al. (US Patent No. 5183493) and Grulke (Polymer Handbook, 1991, 519-524, 526-533, 544-550 and 557-559).

Applicant Claims

Applicants claim a method of preparing gel particles comprising forming a hot aqueous solution of a polymer gelling agent and discharging the hot gelling agent solution through a discharge orifice into a cold moving stream of hydrophobic liquid. The cold hydrophobic liquid being immiscible with the gelling agent solution and being at a temperature below the gelling agent gelling point.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Bretz et al. (US Patent No. 6300468 is serving as the English translation of WO 98/04618 and all referred to column and lines are found in the US Patent) is directed to a process for producing porous polymer globules. The method as taught include dissolving the polymer at temperatures close to the boiling points of the solvents used, such as 100 to 180 °C (column 2, lines 27-40). Then the polymer solution is cooled either quickly or slowly (column 2, line 45). It is taught that it is with the scope of the invention to cool the hot polymer solution by introducing it in a known manner such as spraying or diving it into droplets into a cooling medium such as cold or liquid air, solid carbon dioxide or liquid nitrogen (column 3, liens 25-30). It is taught that when selecting the solvent is it important to choose a solvent in which the polymer has high solubility at elevated temperatures and a low solubility at low temperatures so that as the temperature drops the polymer precipitate (column 2, lines 12-18). It is taught that the size of the polymer beads is affected by the way in which the polymer solution is cooled as well as the cooling times and aging temperature (column 2, lines 56-60). It is taught that if the hot polymer solution is sprayed, atomized or dived into droplets in a cooling

medium mesobeads or macrobeads are obtained with an average diameter of 100 to 200 micrometers and 1000 to 5000 micrometers (1 to 5 mm) respectively (column 3, lines 7-11). It is taught that the polymer beads can be coated or impregnated with known additives such as additives with functional groups, complexing agents, surfactants, porosity affecting agents, etc. (column 3, lines 43-48).

Ascertainment of the Difference Between Scope the Prior Art and the Claims *(MPEP §2141.012)*

Bretz et al. do not teach that the solvent is water. However, this deficiency is cured by Grulke.

Grulke is directed to solubility parameter values. It is taught that the process of dissolving polymers in a solvent is governed by the free energy of mixing (page 519, section 1.1). Table 3.1 is directed to the solubility parameters of various solvents. Table 3.4 is directed to the solubility parameter ranges of commercial polymers.

Bretz et al. do not teach that the how the hot polymer solution is cooled other than indicating that it cooled in known manners for cooling such as dividing it into droplets. However, this deficiency is cured by Brandau et al.

Brandau et al. is directed to the manufacturing of spherical particles. The spherical particles are manufactured by generating droplets by means of a vibrating nozzles and solidification of the droplets so formed in a gaseous or liquid cooling medium (column 1, lines 6-11).The spherical particle size ranges from 5 micrometers to 5 millimeters (column 2, liens 15-20). It is taught that the cooling medium can be lateral to the droplets or in the same direction (column 3, lines 47-50). It is taught that the shape depends on the speed with which the droplets are solidified (column 2, lines

61-62). There is a supply container for the liquid phase, a feed line between supply container and nozzle head, a drop distance, a coolant supply unit and a collecting vessel for the spherical particles (column 4, liens 1-7). With the aid of gas pressure, the liquid phase is passed through the feed line to the nozzle head (column 5, lines 4-6). The use of different sized nozzle heads alters the weight of the resulting particle (column 5, lines 38-40). Exemplified diameters of the nozzle head are 350 micrometers (0.35 mm) and a flow rate of 7.2 ml/min (example 1). It is taught that adjustment of the drop distance adjusts the cooling time of the droplets and subsequently the shape (column 5, lines 58-61). It is exemplified that the microspheres where collected in a container and sieved (example 2).

Finding of Prima Facie Obviousness Rationale and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Bretz et al., Grulke and Brandau et al. and utilize water as the solvent. One of ordinary skill in the art would have been motivated to change the solvent utilized to solubilize the polymer based on the polymer. Bretz et al. teach that the solvent should have a boiling point from about 100 to 180 °C and chosen such that the polymer is soluble in the solvent at elevated temperature and not soluble at lower temperatures so it precipitates out of solution. Grulke teaches the solubility of commercially available polymer. It would have been obvious to one of ordinary skill in the to vary the polymer and subsequent solvent utilized and choose one that the polymer is soluble in only at high temperature in order to form spherical particles as taught by Bretz et al.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Bretz et al., Grulke and Brandau et al. and utilize a dropping device such as that taught by Brandau et al. in order to form the spherical particles. One of ordinary skill in the art would have been motivated to utilize the dropping apparatus taught by Brandau et al. and Bretz et al. teach that the hot solution may be cooled in known manners such as dividing it into droplets into a cooling medium and Brandau et al. teach a dropping device for forming spherical particles.

Regarding the claimed flow rate, both Bretz et al. and Brandau et al. teach that the size of the beads and shape of the beads is controlled by the cooling time. It would have been obvious to one of ordinary skill in the art to vary the flow rate in order to optimize the size of the desired particles. It would have been obvious to one of ordinary skill in the art at the time of the invention to engage in routine experimentation to determine optimal or workable ranges that produce expected results. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. **In re Aller, 220 F. 2d 454, 105 USPQ 233 (CCPA 1955).**

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 33-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bretz et al. in view of Brandau et al. and Grulke and in further view of Tremon (US Patent No. 6096834).

Applicant Claims

Applicant claims that the gelling agent further comprises a dissolved restraining polymer and a labile active agent.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Bretz et al., Brandau et al., and Grulke are set forth above. Specifically Bretz et al. teach formation of spherical particles made from polymers via precipitation. Bretz et al. additionally teach that the polymer beads can be coated or impregnated with known additives such as additives with functional groups, complexing agents, surfactants, porosity affecting agents, etc. (column 3, lines 43-48). It is taught that the additives can be admixed with the polymer solution in dissolved or solid form (column 3, lines 40-42). Brandau et al. teach a device for introducing a hot polymer solution into a cooling medium. Grulke teach the relative solubility of different commercially available polymers in different solvents.

Ascertainment of the Difference Between Scope the Prior Art and the Claims *(MPEP §2141.012)*

Bretz et al. do not teach attaching a labile active agent to a polymer incorporated into the spherical beads. However, this deficiency is cured Tremont.

Tremon is directed to hydrolysable delivery system using cross linked polymer resins as vehicles. The delivery system comprises an active ingredient covalently

bonded to a linker by formation of various bonds which is then bonded to a portion of the subunits of a cross linked polymer (column 1, lines 10-15). It is taught that polymers such as polystyrenes, polyamines, polysaccharides, cellulose esters, etc. can be utilized (column 3, lines 30-60). It is taught that the active ingredient is covalently bonded. Attachment of the active prevents the release of the active until conditions occur which break the covalent bonds. Such conditions for release by the cleavage of the hydrolysable bond will be depend on the condition of the medium into which the delivery system is introduced such as pH or enzymatic content (column 3, lines 18-29). A suitable active agent will be one in which a hydrolysable convent bond with a reactive group on the linker is formed (column 5, lines 30-36). Attachment of a drug to the polymer allows for a controlled release rate of the drug for systemic action (column 5, lines 40-45).

Finding of Prima Facie Obviousness Rationale and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Bretz et al., Grulke, Brandau et al. and Tremon and utilize a linker covalently attached to the polymeric bead and a drug to deliver a drug in a controlled release for systemic action. One of ordinary skill in the art would have been motivated to attach active agent to the polymer beads formed as Bretz et al. teach that additives can be incorporated with the beads and Tremon teaches that attachment of drugs to a polymer allows for controlled delivery of a active agent through a hydrolysable bond. Therefore, when desiring a spherical particle for drug delivery, it world have been obvious to one of ordinary skill in the art to covalently attach a drug to

a polymeric material in order to deliver an active agent in a controlled manner as taught by Tremon.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ABIGAIL FISHER whose telephone number is (571)270-3502. The examiner can normally be reached on M-Th 9am-6pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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